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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,215	12/19/2000	Qi Jia	UNI.15/D	7672

25871 7590 05/21/2002

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EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

BS

Office Action Summary

Application No.
09/741,215

Applicant(s)
Jia et al.

Examiner
Patricia Patten

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 1, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-17, 19, and 21-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-17, 19, and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 13, 15-17, 19 and 21-25 are pending in the application and were presented for examination on the merits.

Applicants arguments with regard to the rejections made in the previous Office Action dated 11/21/01 are moot in light of the new rejections.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 13, 15, 16, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Southard et al. (US 5,013,553).

Claims 13, 15, 16, 21, 24 and 25 are drawn to a method for isolation and purification of an isoquinoline alkaloid via extraction of a ground biomass of a plant with a solvent, neutralization and further concentration. Claims are further drawn to wherein the extract is purified by a chromatographic method, and wherein the plant is selected from a group of specific plant families and genus.

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Southard et al. (US 5,013,553) described a method for isolating benzophenanthridine alkaloids such as chelerythrine and sanguinaria from plants such as *Sanguinaria canadensis* (Family Papaveraceae) via extraction with a mineral acid/alcohol solvent, precipitation with a base and dissolution in water (neutralization), precipitation and drying (concentrating) and further applying to a silica gel column (col.4, line 44- col.5, line 2).

Claim Rejections - 35 USC § 103

Claims 13, 15-17, 19 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southard et al. (US 5,013,553) in view of Mehltrittter et al. (US 2,715,627). Claims 17-20 and 22-23 are drawn to wherein the alkaloid is an aporphine alkaloid such as Magnoflorine or Laurifoline, and wherein the biomass is extracted in a vat extractor or a column extractor, or in a static mode, such as a column extractor.

Taken from the Instant disclosure, a 'vat extractor' appears to be similar to a large blender. One of ordinary skill in the art would have been motivated to have suitably blended the crude plant material/solvent in order to have allowed all of the solvent to penetrate every possible exposed surface area of plant material, which would thereby offer a larger yield of product.

The column extractor, as described in the Instant disclosure (i.e.; p. 17) appears to be a container which holds the crude plant material, whereby said container is provided with an inlet and outlet in order to allow the solvent to pass over the crude plant material and subsequently be

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collected at the outlet. This apparatus would have proven equivalent to mixing the crude plant material with solvent, and then filtering or evaporating the solvent therefrom. It is deemed that the inclusion of the apparatus does not render the invention novel; MPEP 2144.04 III., 'Automating a manual activity', states: 'The court held that broadly providing a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.' In the instant case, although the prior art reference did not use either a vat extraction method, or a column extractor, the manual mixing of the crude plant material with the solvent followed by evaporation and/or removal of the solvent would have accomplished the same results as would a vat extractor and/or column extractor and thus, would have been obvious to one of ordinary skill in the art.

Although the reference did not state wherein a compound such as magnoflorine or laurifoline was isolated via the extraction method, one of ordinary skill in the art would have had a reasonable expectation that alkaloids, having similar isoquinoline structures would have been extracted via the method proposed by Southard et al. (US 5,013,553). One of ordinary skill in the art would have recognized that an extraction with an alcohol and/or acid would have produced a product containing aporphine alkaloids since alkaloids would have had similar polarities due to their phenolic rings. As evidenced by Mehlretter et al. (US 2,715,627), alkaloids such as morphine, a phenanthrene alkaloid, is extracted with mineral acids, neutralization, evaporation and optional purification via column chromatography (col.2, lines 44-65). Thus, although the structure of phenanthrene alkaloids are different, one of ordinary skill in the art would have

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reasonably appraised that the alkaloids of a plant (isoquinoline, aporphine, benzophenanthridine, etc.) could have been extracted with an acid or an alcohol to obtain a crude alkaloid product. The alkaloids would have separated into the acid due to their similar hydrophilic properties.

The method as instantly claimed is a broad extraction method. It appears that the crude product obtained from the one step solvent extraction would yield many alkaloids, necessitating further precise isolation methods such as chromatography in order to purify specific substances.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

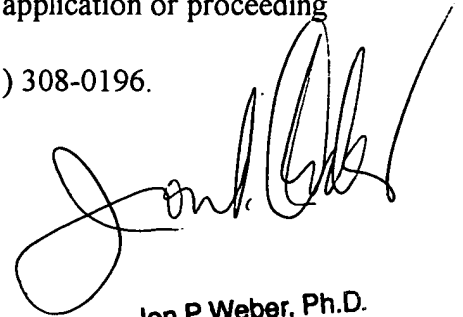
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Jon P. Weber', with a large, stylized flourish extending from the end of the signature.

Jon P. Weber, Ph.D.
Primary Examiner